

Claims 1-14, 16, 19, and 41-43

With respect to claims 1-14, 16, 19, and 41-43, the Examiner argues that Fischer teaches all of the steps of the claims of the present application except for obtaining data indicative of testing specimen outputs of a group of laboratory instruments and normalizing the data according to a control group. The Examiner further argues that Grace teaches the steps and means of obtaining data indicative of outputs of a group of laboratory instruments and normalizing the data according to a control group, and states that it would have been obvious to one having ordinary skill in the art to include the Grace "group data collection and normalization" technique in the Fischer method in order to arrive at the claimed invention.

Grace is directed to a method of normalization of experimental data to account for experiment-to-experiment variability introduced by an environment. The method is used to reduce variability introduced by the single environment in which multiple iterations of the same experiment are conducted (Abstract, lines 1-6). Thus, Grace teaches a method of removing environmental error introduced when repeatedly running the same test, over and over, on a single instrument, in a single location. There is absolutely no teaching, disclosure, or suggestion in Grace that data may be collected from multiple instruments, that data may be collected from multiple locations, or that normalization of data from multiple instruments may be performed. The problems presented by normalizing data from multiple repetitions of the same test, on the same instrument, in the same location, as in Grace, are non-analogous to those solved by the claimed invention, which is directed to normalizing data from multiple instruments at multiple locations. Two of the citations to Grace by the Examiner purporting to teach obtaining data indicative of outputs of a group of laboratory instruments and normalizing the data according to

a control group (namely, col. 3, lines 2-24, and lines 38-41) in fact simply discloses collecting multiple data sets of experimental data from repeatedly running the same test and normalizing the data to reduce experiment-to-experiment variability (Grace, col. 3, lines 17-19 and lines 40-41).

The other Grace citations provided by the Examiner purporting to teach obtaining data from a group of laboratory instruments and normalizing the data according to a control group (namely, FIG. 2, and col. 8, lines 10-25) simply refer to a single, multi-component data signal collected when analyzing biotechnology data. As described in Grace, laser-induced fluorescence and electrophoresis is used to obtain the complex, multi-component data signal based on an indicated fluorescence intensity of the biotechnology specimen (col. 7, lines 50-60). The response from the fluorescence intensity test is relatively broadband, and includes spectral overlap (col. 7, lines 50-65). In other words, the data obtained from a single fluorescence test contains a significant amount of data indicative of responses in multiple spectral bands, thus the data signal having information relating to the responses in several spectral bands is a multi-component data signal that has been generated by a single test on a single instrument. Grace, however, does not teach, suggest, or disclose obtaining data from multiple instruments or normalizing data from multiple instruments. By contrast, the claims of the present invention are directed to obtaining data indicative of outputs of a group of laboratory instruments and then normalizing the data from that group of instruments.

The Examiner admits that Fischer does not teach obtaining data indicative of outputs of a group of laboratory instruments and normalizing the group data according to a control group. As discussed above, Grace likewise does not teach obtaining data indicative of a group of laboratory instruments and normalizing the group data according to a control group.

Since neither Fischer nor Grace teach obtaining data indicative of outputs of a group of laboratory instruments and normalizing the instrument group data to a control group, the combination of Fischer and Grace does not teach the claimed invention. For this reason, the Examiner's rejection of claims 1-14, 16, 19, and 41-43 should be withdrawn.

Furthermore, as stated in MPEP §2143.01, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. Fischer is directed to a fully automated analyzer and method for testing blood samples in a clinical laboratory (Abstract, lines 1-3). As described in Fischer, the analyzer is adapted to automatically handle a high throughput of samples (Col. 4, lines 3-6). Grace, on the other hand, teaches only a data processing method, in which the data being processed has been collected from a generic analyzer in any of several scientific fields (FIG. 1, col. 10, lines 1-7). There is absolutely no suggestion in Fischer to include a separate, stand-alone data processing capability, likewise, there is absolutely no suggestion in Grace to provide an integrated analyzer capable of achieving a high-throughput of specimens. Thus, since there is no suggestion in either Fischer or Grace to make the hypothetical combination, the rejection of claims 1-14, 16, 19, and 41-43 is unsupported by the art and should be withdrawn.

In addition, since Fischer teaches a self-contained, automated, high-throughput analyzer, and Grace teaches a stand-alone data processing method, Fischer and Grace in fact teach away from the Examiner's proposed combination. One skilled in the art would not normally turn to two diametrically opposed technologies to come up with a solution to a problem neither reference even contemplated. As stated in MPEP §2145, it is improper to combine references where the references teach away from their combination. For this additional

reason, the rejection of claims 1-14, 16, 19, and 41-43 is unsupported by the art and should be withdrawn.

Claims 21-36 and 39-40

With respect to claims 21-36 and 39-40, the Examiner argues that the combination of Fischer and Grace teaches a method and system that includes all of the subject matter of the claimed invention except for modifying data from more than one group of laboratory instruments, and that it would have been obvious to one having ordinary skill in the art to apply the method of the hypothetical Fischer and Grace combination to more than one group of laboratory instruments.

As discussed above with respect to claims 1-14, 16, 19, and 41-43, neither Fischer nor Grace disclose, teach, or suggest collecting, normalizing, or modifying data from anything other than a single source, instrument, or repetition of tests in a single environment. There is absolutely no teaching, suggestion, or disclosure in either Fischer or Grace that teaches obtaining data indicative of outputs of a group of laboratory instruments and normalizing the group data to a control group as in the claimed invention. Thus, the Examiner's rejection of claims 21-36 and 39-40 should be withdrawn.

Furthermore, MPEP §2143.01 states that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. As discussed above with respect to claims 1-14, 16, 19, and 41-43, there is absolutely no suggestion in Fischer to include a separate, stand-alone data processing capability as in Grace. Likewise, there is absolutely no suggestion in Grace to allow an integrated analyzer capable of achieving automatic, high-throughput as in Fischer. Thus,

since there is no suggestion in either Fischer or Grace to make the suggested combination, the rejection of claims 21-36 and 39-40 is unsupported by the art and should be withdrawn.

In addition, since Fischer teaches a self-contained, automated, high-throughput analyzer, and Grace teaches a stand-alone data processing method, Fischer and Grace in fact teach away from the Examiner's proposed combination. As stated in MPEP §2145, it is improper to combine references where the references teach away from their combination. Thus, for this additional reason, the rejection of claims 21-36, and 39-40 is unsupported by the art and should be withdrawn.

#### Claims 45-54

With respect to independent claim 45, and dependent claims 46-54, the Examiner argues that Fischer teaches the method claimed in the present application except for standardizing instrument results from a plurality of laboratory instruments, and that it would have been obvious to apply the Fischer and Grace techniques to a group of laboratory instruments.

As discussed above, Fischer discloses an automatic analyzer which itself collects data and normalizes the collected data. There is absolutely no disclosure, teaching or suggestion in Fischer to obtain data from more than one analyzer and to standardize the results from those analyzers, as required in the claims of the present application. As also discussed above, Grace discloses a method of normalizing data collected from repeatedly running a test in a single environment. There is absolutely no disclosure, teaching, or suggestion in either Fischer or Grace that would lead one skilled in the art to combine Fischer and Grace to arrive at the invention as claimed in the present application, where data from a plurality of laboratory

instruments is standardized. Thus, the Examiner's rejection of claims 45-54 is improper and should be withdrawn.

Furthermore, even if the standalone analyzer of Fischer were combined with the method of processing data from a single environment of Grace, the resultant combination would not disclose standardizing data from a plurality of laboratory instruments, as in the claimed invention. For this reason, too, the Examiner's rejection of claims 45-54 should be withdrawn.


Claims 20 and 55

Claim 20 depends from claim 1, discussed above with respect to claims 1-14, 16, 19, and 41-43. Claim 55 depends from claim 45, discussed above with respect to claims 45-54. Since claims 1 and 45 are allowable for the reasons discussed above, claims 20 and 55 are thus also allowable.

In view of the foregoing remarks, it is respectfully submitted that all claims of the application are now in condition for allowance and eventual issuance. Such action is respectfully requested. Should the Examiner have any further questions or comments which need be addressed in order to obtain allowance, he is invited to contact the undersigned attorney at the number listed below.

Acknowledgement of receipt is respectfully requested.

Respectfully submitted,

By:   
Mark C. Young, Reg. No. 48,670  
STINSON MORRISON HECKER LLP  
1201 Walnut Street, Suite 2800  
Kansas City, MO 64106-2150  
Telephone: (816) 842-8600  
Facsimile: (816) 691-3495  
Attorney for Applicant